Model 1029 User Manual

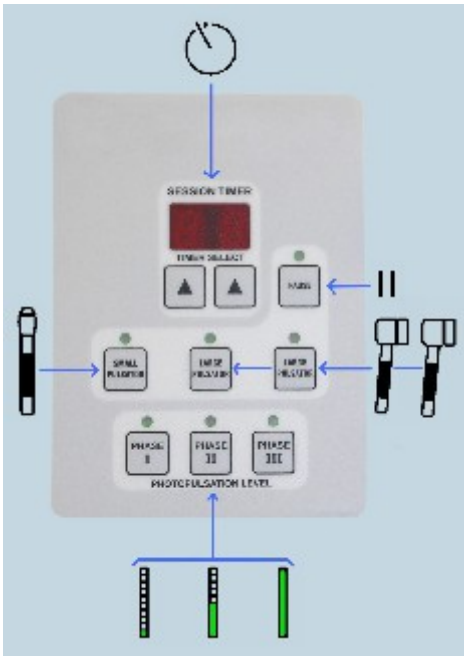
TABLE OF CONTENTS

SETUP....2
FUNCTION....2
TREATMENT....3
INDICATIONS FOR USE....3
CONTRAINDICATIONS....3
CLEANING....4
MAINTENANCE....4
CLASSIFICATION & SYMBOLS....4
DISINFECTION / STERILIZATION....4
SAFETY PRECAUTIONS....4
SPECIFICATIONS....5
CONTACT INFORMATION....6
APPENDIX A: GUIDANCE AND MANUFACTURER'S DECLARATION - EMC....7

SETUP

FUNCTION

Turn the unit on by pressing the black switch on back . The session timer will display 00. **Note:** If **P** or **PP** appears in the display it indicates that a pulsator is missing or not connected correctly. Turn unit off and check pulsator connections.



TREATMENT

Make sure you read and understand all the information contained in this manual before operating unit.

1 For: ACNE USE BLUE PULSATOR, PAIN TREATMENTS USE RED or AMBER PULSATORS and for SKIN TREATMENTS USE RED PULSATORS.

2 Snap on the disposable cover.

3 Set timer: Acne = 20 minutes or Pain / Skin = 10 minutes

4 For ACNE or PAIN TREATMENTS, select Phase II. For SKIN TREATMENT select PHASE I or II for the first and second treatment and PHASE III for all subsequent treatments.

5 Press the large pulsator button to activate. Start by touching the large pulsator to the skin (⚠At no time should the pulsator be brought into contact with the skin surface of the wound area. See precautions concerning skin contact.) Move pulsator (25% overlap) when beep sounds (every 10 seconds). Problematic acne areas should be treated longer (up to 90 seconds). Continue treating the area.

   For SKIN TREATMENTS, select PAUSE after the area has been treated with the large pulsator. Remove - dispose of pulsator cover and place large pulsator in holder. Remove the small pulsator from the cradle and snap on the disposable cover. (Note: squeeze small pulsator cover before snapping it on the small pulsator for a tighter fit.) Press the small pulsator button to activate. The beep will sound every 18 seconds to remind you to move from one area to another covering the crow's feet, under the eyes, on the nose, along side the nose, and by the mouth Problematic areas should be treated with up to 90 seconds (5 beeps) of LED light therapy over each area for maximum effect. Besides using a circular motion, vary the movement with zigzag and straight patterns on the wrinkles and fine lines. If you need more time, press PAUSE and add minutes to the session timer.

6 When session timer shows “00”, the pulsator turns off, treatment is complete.

7 Remove - dispose of pulsator cover and place pulsator in holder.

INDICATIONS FOR USE

The Model 1029 utilizes Light Emitting Diodes to provide light to the body. Generally indicated to:

- treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris (Blue Pulsators);
- provide topical heating to promote increased blood flow, relaxation of muscle and relief of pain (Amber/Red pulsators)

CONTRAINDICATIONS

Do not use on anyone that is pregnant, has epilepsy or is using any medication that is known to cause light sensitivity, e.g., tetracycline or Retin-A.

CLEANING

Cabinet As required perform the following:

	Disconnect the power cord from electrical outlet before cleaning unit / accessories.
	Do not use petroleum-based solvents / cleaners. Do not use liquid directly on the unit / accessories.
	Clean cabinet / accessories with mild soap and water applied with a damp cloth - wipe dry.

MAINTENANCE

	If the device is observed to not be operating properly, then discontinue use immediately and contact your distributor for service.
	No periodic service / maintenance requirements.
	Control unit / pulsators are calibrated. Repairs must be performed by the manufacturer and verified to original standards. Contact your distributor concerning repair to prevent voiding the warranty.
	When disposing of this device or any accessories, make certain to abide by your local waste disposal regulations.

CLASSIFICATION & SYMBOLS

	IEC 60417-5172	CLASS II EQUIPMENT. **This device is Class II Equipment.** Protection from electric shock is achieved by DOUBLE INSULATION
	IEC 60417-5333	TYPE B APPLIED PART. **This device utilizes Type B Applied Parts.** Equipment Equipment providing a particular degree of protection against electric shock, particularly regarding: 1) allowable leakage current.
	ISO 7000-0434A	Caution / Read Instructions for use
	ISO 7010-M002	Follow instructions for use

DISINFECTION / STERILIZATION

	No disinfection / sterilization requirements. Read safety precautions concerning skin contact.

SAFETY PRECAUTIONS

	Use only GlobTek power supply model GMT21089-1815-T3, REF G1200LCP-Y-MED. Replacement, contact distributor - request replacement REF 62-0000150.

⚠	To fully isolate the Model 1029 from the supply mains, unplug the AC cord from the power supply.
⚠	Only attach accessories specifically provided for use, with the Model 1029. Attaching any accessory or device not intended to be used with the Model 1029 will compromise safety and may damage the equipment.
⚠	The pulsators are intended for direct contact with healthy skin only. Do not place the pulsators directly in contact with injured or damaged skin surfaces. The light may be applied to injured areas but the pulsators must be held away from the skin surface.
⚠	Do not apply the pulsator directly to the skin when the ambient temperature is above 32 C (90 F).
⚠	This device has been tested for EMC compliance with IEC60601-1-2(2007), EN61000-3-2(1995) and EN61000-3-3(2006). Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF communications equipment can affect medical electrical equipment. The use of accessories, transducers, and cables other than those specified by the manufacturer , may result in increased emissions or decreased immunity of the equipment or system. The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which is will be used. Should interference be noted: - reorient or relocate the equipment. - increase separation between the equipment. - connect equipment into a different circuit.
⚠	EQUIPMENT NOT SUITABLE for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.
⚠	Do not shine pulsators directly into the eyes, apply treatment on the upper eye lids or directly over thyroid gland (center of neck).
⚠	Administer only after physician consultation if patient 1) is pregnant, 2) has epilepsy, and 3) taking any medication that would cause a sensitivity to light such as tetracycline or acutane, 4) any skin conditions that would be negatively affected by light stimulation.
⚠	Indoor use only.
⚠	Do not operate near water.
⚠	Do not connect pulsators while active - must be in pause mode or turned off.

SPECIFICATIONS

SYSTEM	⚠
Movement Guide	Audible Beep: Large/Double Pulsator every 10 seconds; Small Pulsator every 18 seconds
Session Timer	Countdown, 1-99 minutes
Photopulsation Level	PHASE I, II, III each have a weighted group of photomodulation frequencies. Light power is reduced ≈10% per phase from Phase III. Frequencies* (Hertz - duration is seconds) PHASE I - 73Hz-1s, 292Hz-1s, and 584Hz-1s. PHASE II - 73Hz-2s, and 584Hz-1s. PHASE III - 73Hz-4s, and 584Hz-1s. * Frequencies sequentially selected

Power Supply ⚠	Input: 100-240VAC , 50-60Hz @ 1.0A, IEC C14 receptacle. Output:15VDC power input at 1.2A GlobTek only, REF 62-00000150
Warranty	Contact distributor for warranty term and coverage.
Expected Service Life	5 years
Environmental	Operating ambient temperature range of +10°C (50°F) to +40°C (104°F) Operating humidity maximum 95% RH (no condensation) Operating atmospheric pressure 22.7 inHg to 31.3 inHg (70 kPa to 106kPa) Operating altitude ≤ 2000m, Pollution degree 2 (office environment)
Shipping / Storage	Dimensions: 61cm (24") x 36cm (14") x 20cm (8") Weight: 5kg (11 lbs.) Temperature: -20°C (-4°F) to 50°C (122°F) Humidity max.: 95% RH (no condensation)
Pulsators	⚠
Treatment area:	Small Pulsator - 1 cm2 Large Pulsator - 9 cm2 Double Pulsator - 19 cm2
Cable	61cm (24") coiled, 1:5 extension ratio
Thermal ⚠	Large / double pulsators will elevate skin temperature to 40°C - 45°C (104°F - 113°F).
Small Red	1 LED, 625nm @ 40mW Phase III - 10mW/cm2
Large (Double) Red	1 (2) LED, 625nm @ 160mW + optics 12 (24) infrared LED, 940nm @ 20 mW Phase III - 80mW/cm2
Large (Double) Amber	1 (2) LED, 590nm @ 80mW + optics 12 (24) infrared LED, 940nm @ 20 mW Phase III - 25mW/cm2
Large (Double) 420 Blue	1 (2) LED, 455nm @ 100mW + optics 12 (24) LED, 420nm @ 18 mW Phase III - 45mW/cm2
Large (Double) 420 Red	1 (2) LED, 625nm @ 160mW + optics 12 (24) LED, 420nm @ 18 mW Phase III - 80mW/cm^2

CONTACT INFORMATION

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APPENDIX A: GUIDANCE AND MANUFACTURER'S DECLARATION - EMC

Note- Essential Performance: for the purpose of EMC compliance, no device functions are considered essential to the safety of the user or patient.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 1029 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 1029 should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Model 1029 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Model 1028 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 1029 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 1029 should assure that it is used in such an environment			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact *per guidance* ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. *Contact discharge can cause the Model 1029 to turn off or to become unresponsive and may require manually restart by cycling power switch. Operation interruption does not present a hazard in regards to functional safety and essential performance. Model 1029 tested device had metal pulsator enclosures and connectors which were subsequently changed to plastic removing ESD contact discharge points.*
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines *per guidance* ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. *Some electrical fast transient/burst conditions can cause the Model 1029 to turn off or to become unresponsive and may require manually restart by cycling power switch. Operation interruption does not present a hazard in regards to functional safety and essential performance. It may be necessary to position the Model 1029* *further from sources electrical fast transients by connecting it to a different electrical outlet or providing power line conditioning.*
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 1029 requires continued operation during power mains interruptions, it is recommended that the Model 1029 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 1029 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 1029 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Model 1029, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ **80 MHz to 800 MHz** $d = 2,3\sqrt{P}$ **800 MHz to 2,5 GHz** where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 1020 is used exceeds the applicable RF compliance level above, the Model 1029 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 1029. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the Model 1029			
The Model 1029 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 1029 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 1029 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz **d = 1,2 √P**	**80 MHz to 800 MHz** **d = 1,2 √P**	**800 MHz to 2,5 GHz** **d = 2,3 √P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			